No. 74-215

IN THE

Supreme Court of the United States

OCTOBER TERM, 1974

UNITED STATES OF AMERICA, *Petitioner*

v.

JOHN R. PARK

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR NATIONAL CANNERS ASSOCIATION, AMICUS CURIAE

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Amicus submits this brief in support of the Respondent John R. Park. All parties have consented to its filing by a letter which has been presented to the Clerk of the Court pursuant to Rule 42(2).

INTEREST OF AMICUS

The National Canners Association is a nonprofit trade association of approximately six hundred members who have canning operations in forty-four states and the territories. Members of the Association pack

eighty to ninety percent of the entire national production of canned fruits, vegetables, juices, specialties, meat, and fish. Many aspects of its members' operations are subject to the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. §§ 301-392 (1970) ("the Act") and numerous comprehensive and technologically complicated regulations promulgated thereunder.

INTRODUCTION AND SUMMARY OF ARGUMENT

This case involves the standard of individual criminal liability under the Act applicable to officers and employees of a corporation when violations of the Act and the extensive regulations under it occur in the course of the corporation's business.

Nearly all of the Association's members are corporations whose officers and employees may be directly affected by the articulation of that standard by this Court. The Association believes that any penal standard must protect both consumers and the rights of the officers and employees of its members. Since, under the Act, individuals may be sentenced to prison, [1] and upon a second conviction are branded as felons, [2] special considerations of justice and fair play must be taken into

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[1] Section 303(a) of the Act, 21 U.S.C. § 333(a) (1970), provides:

"(a) Any person who violates a provision of section 301 shall be imprisoned for not more than one year or fined not more than $1,000, or both."

[2] Section 303(b) of the Act, 21 U.S.C. § 333(b) (1970), provides:

"(b) Notwithstanding the provisions of subsection (a) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both."

account in defining that standard. Since these considerations are largely inapplicable to corporations, the Association's views expressed here are limited to the question of *individual* criminal liability.

Some thirty years ago, in *United States* v. *Dotterweich*, 320 U.S. 277 (1943), this Court held that an individual may be criminally liable for violations occurring in the course of a corporation's business if the "evidence produced at trial" shows the individual to have had "*a responsible share* in the furtherance of the transaction . . . ." 320 U.S. at 284 (emphasis added). At that time, the Court declined to define the class of employees having such a "responsible share" leaving the question for "submission . . . to the jury under appropriate guidance." *Id.* at 285.

Dotterweich involved a business where every management decision was made by a single individual acting directly as President and General Manager of a company with 26 employees at one location—three decades ago.[3] Since *Dotterweich,* the country's economy has evolved to a point where most of the goods covered by the Act are produced and distributed by corporations having chains of management command which necessarily function by delegation.

Many members of the Association have scores of packing plants and warehouses located throughout the nation and employing tens of thousands of employees. The management of these companies must necessarily function by delegating operational authority to sub-

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[3] The factual situation in *Dotterweich* was reviewed by the Court of Appeals in this case and is summarized in the opinion below. United States v. Park, 499 F.2d 839, 841 n. 3 (4th Cir. 1974).

ordinates, in large part because of the physical separation between management—usually located at a corporate headquarters and the various processing operations—which must be located close to where different crops are grown.

Another factor which has lead to an increased need for delegation of operational authority, particularly with respect to compliance with the Act, has been the increasingly complex technical requirements imposed by the Food and Drug Administration ("FDA") under the Act since *Dotterweich*. These now fill six volumes of the Code of Federal Regulations.[4] In the case of the canning industry, regulations prescribe virtually every step of the canning process and are so technical and complex that they are literally unintelligible to those who lack complete technological training in these areas.

One need merely examine, as an example, the regulations applicable to "Thermally Processed Low-Acid Food Packaged in Hermetically Sealed Containers (21 C.F.R. Part 90 (1974); 21 C.F.R. Part 128b (1974)), to comprehend that only a specially trained individual can be expected to understand and implement those requirements. Indeed, the regulations specifically provide that the processing be conducted:

> ". . . under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction in retort operations, processing systems operations, aseptic processing and packaging systems operations, and container closure inspections, and has been identified by that school as having satisfactorily com-

[4] 21 C.F.R. §§ 1-1401.73 (1974).

pleted the prescribed course of instruction." (21 C.F.R. § 128b.10).

Similarly detailed regulations, the interpretation of which may require medical, engineering, statistical and other forms of technical expertise, apply to the manufacturing and labeling of drugs, cosmetics and medical devices.[5] In some instances, these regulations are unrelated to any hazard to health and involve purely economic issues such as the proper type size and label format for stating net quantities of content in food packages.[6]

Since no company president can be expected to develop the requisite expertise in each of the fields needed

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[5] *See, e.g.*, the current labeling requirements for certain medical diagnostic devices. 21 C.F.R. § 328.10 (1974). Among the most detailed of FDA's current labeling schemes, four pages of these regulations list required labeling information including:

"[d]etails of calibration: Identify reference material. Describe preparation of reference sample(s), use of blanks, preparation of the standard curve, etc. The description of the range of calibration should include the highest and the lowest values measurable by the procedure.

. . . .

(11) Expected values: State the range(s) of expected values as obtained with the product from studies of various populations. Indicate how the range(s) was established and identify the population(s) on which it was established.

(12) Specific performance characteristics: Include, as appropriate, information describing such things as accuracy, precision, specificity, and sensitivity. These shall be related to a generally accepted method using biological specimens from normal and abnormal populations. Include a statement summarizing the data upon which the specific performance characteristics are based."

21 C.F.R. § 328.10(b)(8)(v), (11) and (12) (1974).

These requirements alone require expertise in medicine, chemistry and statistics.

[6] *See, e.g.*, 21 C.F.R. § 1.8b (1974).

to interpret and implement compliance with the bulk of the FDA's present regulations, he must rely on technically trained subordinates. Top management is equally dependent on these qualified personnel for information as to any problems which might arise with respect to compliance. While a layman may be in a position to detect grossly insanitary conditions which are apparent to the naked eye, if he has the opportunity personally to scrutinize every canning plant or warehouse, he must rely on the assurances of others on such questions as whether sufficient samples are being tested to support a statistically sound quality control program.

It is against this background that trial courts today must consider and charge juries as to, under what circumstances, it is consistent with the intent of Congress and the purposes of the Act to impose absolute criminal sanctions, absent knowledge or intent, on chief executive officers and other management personnel for corporate violations, which may be based on a failure of a remote subordinate to conform to one of the massively detailed and technically complex regulations which the FDA routinely and increasingly promulgates under the Act today.[7]

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[7] Criminal prosecution of individuals under the Act are a frequent, if not everyday occurrence. A recent study of the agency's enforcement activities reveals that in 1973 approximately 90 criminal cases were forwarded to United States Attorneys for prosecution and in most, consistent with the FDA's policy, at least one responsible individual was charged. The United States Attorneys and the Department of Justice declined to prosecute only a very small percentage of these cases. *See* O'Keefe and Shapiro, *Personal Criminal Liability Under the Federal Food, Drug, and Cosmetic Act The Dotterweich Doctrine*, 30 Food Drug Cosm. L.J. 5, 27 (1975).

In the cases since *Dotterweich,* where individual defendants have denied having a "responsible share" in the transaction, the reported opinions of trial and appellate courts have generally justified a conviction with little more than a citation to or quotation from the rhetoric in *Dotterweich.*[8] In those cases it is clear that the individual defendants were intimately involved in and usually present on a day-to-day basis at the local site of the operations giving rise to the violations. Whatever may be said of the manner in which lower courts have dealt with that situation, as this case so clearly demonstrates, that approach is no longer adequate, in view of the changes in the regulated industries and the requirements under the Act since *Dotterweich.* One thing is clear. Some defined direction to lower courts is needed.

The difficulties inherent in applying a standard enunciated in a case involving a one man operation with 26 employees to the realities of today's disparate mass production have prompted some commentators to ask:

> "[w]ho has, and under what conditions does he have, 'a responsible share in the furtherance of

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[8] *See,* United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971); Lelles v. United States, 241 F.2d 21 (9th Cir.), *cert. denied,* 353 U.S. 974 (1957); United States v. Hohensee, 243 F.2d 367 (3d Cir. 1957); United States v. H. Wool & Sons, Inc., 215 F.2d 95 (2d Cir. 1954); Golden Grain Macaroni Co. v. United States, 209 F.2d 166 (9th Cir. 1953); United States v. Kaadt, 171 F.2d 600 (7th Cir. 1948); United States v. Colosse Cheese and Butter Co., 133 F.Supp. 953 (N.D.N.Y. 1955); United States v. Diamond State Poultry Co., 125 F. Supp. 617 (D. Del. 1954). United States v. Parfait Powder Puff Co., 163 F.2d 1008 (7th Cir. 1947), *cert. denied,* 332 U.S. 851 (1948), cited by the Government in support of its view of the proper standard for individual liability (Govt. Brief at 25-26), is far wide of the mark. There was no individual defendant in the case.

the transaction which the statute outlaws'? When does he 'aid and abet' in the commission of the violative acts? When does he share 'responsibility in the business process resulting in unlawful distribution'?

"Sufficient time has elapsed since 1943, sufficient cases have been before the courts, and there is sufficient confusion on the point to warrant Supreme Court guidance. Hopefully, such guidance will be forthcoming from the Court, which has granted *certiorari* in the *Park* case."[9]

The Association believes that the opinion of the Court of Appeals below offers both a realistic and just approach to this question and presents this Court with an opportunity to give the lower courts the wise guidance which they will require vigorously yet fairly to apply the criminal sanctions of the Act to individuals.

The Court of Appeals held that in a prosecution of an individual under the Act "a finding of guilt must be predicated upon some wrongful action by [that individual]." 499 F.2d at 842. Recognizing that *Dotterweich* construed that Act as doing away with the usual requirement that the Government prove "awareness of wrongdoing", the Court stated that the "Government has confused the element of 'awareness of wrongdoing' with the element of 'wrongful action'; *Dotterweich* dispenses with the need to prove the first of those elements but not the second." *Id.* at 841. The Court of Appeals went on to hold that the individual's wrongful action may be "any of a host of . . . acts of commission or omission which would 'cause' the [violation]." *Id.* at 842. The Court of Appeals' choice of language also suggests that the act of commission or omission must,

[9] O'Keefe and Shapiro, *supra* note 7 at 24.

in some way, fall short of the standard of conduct which Congress sought to promote by the Act.

The standard enunciated by the Court of Appeals is consistent with the plain language of the statute, *Dotterweich,* subsequent cases in this Court relying or commenting upon *Dotterweich,* and most importantly, Congress' purpose in passing the Act. That standard will allow for vigorous enforcement of the Act without subjecting individuals to the *in terrorem* effect of a severe absolute penal sanction restrained only by the private judgment of those charged with its enforcement.

The language of the Act only prohibits the causing of certain acts and the failure to perform others.[10] Nothing in the statute remotely suggests that it is intended to criminalize the status of holding any particular corporate position or "standing" in any kind of "relationship" to a violation unless that relationship is defined in terms of an individual's conduct.

This was recognized in *Dotterweich,* where this Court made clear that an individual's "responsible relationship" to a situation, which might justify individual criminal liability, must necessarily be assessed in terms of those "settled doctrines of criminal law" employed to define those who, though not principal perpetrators of a crime, may be held liable as accessories, and in particular, as aiders and abettors. 320 U.S. at 284. Those doctrines require that an individual "associate himself with the venture . . . participate in it [and] . . . seek by his action to make it succeed." *United States* v. *Peoni,* 100 F.2d 401, 402 (2d Cir. 1938). The Court went on to stress that responsible relationships should

[10] 21 U.S.C. § 331.

be defined in terms of the "variety of conduct" in which the individual may have engaged. 320 U.S. at 285.

Subsequent to *Dotterweich*, this Court confirmed its original reliance on conduct in *Dotterweich* by contrasting *Dotterweich* with attempts to punish behavior that is "wholly passive". *Lambert* v. *California*, 355 U.S. 225, 228 (1957). More recently, this Court has "followed" *Dotterweich* in applying the criminal sanctions of § 1 of the Sherman Act to a corporate officer who "authorizes, orders, or helps perpetuate the crime." *United States* v. *Wise*, 370 U.S. 405, 416 (1962).

The Government's position on this issue is far from clear. Since it rested its case-in-chief after showing only that Park was Acme's president and that Acme's by-laws provided that he should "have general and active supervision of the affairs, business, offices, and employees of the company," (Govt. Brief at 6-7) it appears that the Government initially sought to rely solely on proof of Park's corporate position to establish his guilt. While in its Brief here, the Government now seems to concede that it must show some acts of commission or omission and prove "actual supervisory responsibility," (Govt. Brief at 25) the Government does not begin to define just what kind of acts it should be required to prove.

Despite the Government's protestations to the contrary, one is left with the clear impression that it seeks to rely on proof of an individual's corporate position buttressed, at most, by a showing of titular power and opportunity generally to influence the operations of the corporation which gave rise to the violation of the Act. That suggested standard, which is unrelated to an in-

dividual's actual conduct, knowledge or intent, bears no rational relationship to the purpose of the statute—which is clearly to influence behavior—not punish status.

In contrast to the Government's position, the standard enunciated by the Court of Appeals, requiring the Government to prove an act of commission or omission which "causes" a violation, is the traditional and time-tested judicial approach which focuses on conduct and reality.

In light of the clearly erroneous theory of the Government's case, upon which the trial court relied in instructing the jury, the Court of Appeals was not required to consider (if any of Park's acts of commission or omission caused a violation) whether the Government should have to show that Park's conduct fell below the standard which Congress sought to promote by the act. Nonetheless, the Court of Appeals' choice of the word "wrongful", as opposed to "causitive" suggests that it was sensitive to that issue.

The Federal Food, Drug, and Cosmetic Act is an example of a special form of legislation imposing criminal liability without regard to knowledge or intent for what have come to be known as public welfare offenses.[11] As this Court held in *United States* v. *Balint*, 258 U.S. 250 (1922), in such instances Congress may properly relieve the Government of its traditional burden of proving knowledge or intent in the interest of efficient enforcement. The purpose of such statutes is protection of the public, not punishment of an evil intent. The absence of consciousness of wrongdoing is

[11] *See* Sayre, *Public Welfare Offenses*, 33 COLUM. L. REV. 55 (1933).

considered irrelevant. These statutes are designed to protect the public by "stimulat[ing] proper care." *Id.* at 253. That principle, enunciated in *Balint* and relied on in *Dotterweich,* finds limitations in its rationale. If an individual is to be stimulated to take proper care by the threat of criminal sanction for his failure to do so, he must be aware that some problem exists and that, therefore, there is some need to take special precautions or corrective measures. In short, if an individual could not have reasonably foreseen that the consequences of an act or omission might be a violation of the Act, he should not be held criminally liable. In the language of *Dotterweich,* he did not have "the opportunity of informing [himself] of the existence of the conditions" which might result in violations. 320 U.S. at 385.

The Government appears to acknowledge this limitation on *Dotterweich* when it states that individuals:

> "who were totally unaware of any problem and could not have been expected to be aware of it in the *reasonable* exercise of their duties are not the subject of criminal action." Govt. Brief at 31. (emphasis added).

Just as there is no purpose in punishing individuals for unforeseeable consequences of their acts or omission, once a person has taken every reasonable precaution to prevent violations of the Act, at that point, threat of criminal sanction, however severe, cannot stimulate greater care.

This was recognized in *Morissette* v. *United States,* 342 U.S. 246 (1952), where the Court suggested that public welfare statutes hold individuals to only a "reasonable" standard, and subsequently, in *United*

States v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964), when this Court noted that the Act's criminal sanctions were not intended to apply to those who are "'powerless' to protect against" the violation. 376 U.S. at 91. Consistent with this view, the legislative history of the 1938 Act suggests that Congress intended to punish only those who cause violations through "inadvertence, carelessness or negligence," S. Rep. No. 493, 73d Cong. 2d Sess. 20 (1934), and nothing in the subsequent legislative history of amendments and proposed amendments to the Act suggests to the contrary.

In considering the impact of affirming the Court of Appeals, this Court should keep two principal issues in mind: the effect that the Court of Appeals' standard would have on enforcement of the Act and the effect that adoption of the Government's position would have on the rights of individuals.

The Government would have this court believe that adoption of the standard enunciated by the Court of Appeals would leave enforcement of the Act in a shambles. Nothing could be further from the truth. Criminal prosecutions of individuals is but one of the arsenal of sanctions effectively available to the FDA to secure compliance with the Act. The FDA has the statutory power to seize goods that violate the Act wherever they may be found and where there is a threat to the public health; the statute authorizes seizures which literally result in destruction of the offending goods.

The FDA can also proceed by way of injunction against both individuals and corporations. This can effectively close down an entire food processing plant and may in effect put it out of business for good. In the case of canned foods, special statutory authority

allows the FDA to require a canner to conduct his operations pursuant to a permit spelling out, in detail, the precautions which must be taken to protect the public. Finally the FDA is authorized by statute to fully and immediately publicize violations involving hazards to the public health or gross frauds that publicly cannot only protect the public but may also put the violator permanently out of business.

In addition to its statutory authority, the *threat* of statutory action allows the FDA to pressure manufacturers into engaging in "voluntary" recalls. These are, in effect, self-imposed seizures and injunctions. In fact, all of the problems which the FDA has raised with the Court of Appeals' standard are straw-men and do not present any practical hurdles to the Act's vigorous enforcement. This is clearly indicated by the fact that the FDA's current enforcement policies and procedures are entirely consistent with the Court of Appeals' standard.

While the impact of the Court of Appeals' standard on the enforcement of the Act is minimal, were this Court to embrace the Government's position, it would create a situation unparalleled in this country's judicial history. Because of the inevitability of technical violations, which can be made out on the basis of failure to conform to one of the FDA's comprehensive, technically complex and sometimes unclear regulations, the Government standard would place every executive of a firm making or dealing in products regulated under the Act, in a position where his civil liberties existed "on the basis solely of the private judgment of his prosecutors." [12]

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[12] Hart, *The Aims of the Criminal Law*, 23 LAW & CONTEMP. PROB. 401, 424 (1958).

While no suggestion is made that the FDA seeks this awesome power to abuse it, even recent history teaches that this country must remain a government of laws and not men. As time worn as the phrase may be, Lord Acton was correct in admonishing that "absolute power corrupts absolutely." [13]

Since the trial court's instructions to the jury clearly adopted the Government's extreme and unwarranted view of *Dotterweich* and thereby created a substantial probability that the jury convicted Park solely on the basis of his corporate position, without regard to his conduct, the Court of Appeals' must be affirmed.

ARGUMENT

I. The Court of Appeals Correctly Interpreted the Act and Dotterweich as Requiring the Government, in a Criminal Prosecution of an Individual, To Prove an Act of Commission or Omission by the Defendant.

In the decision below, the Court of Appeals correctly held that the Act, as interpreted by this Court in *Dotterweich*, requires proof of wrongful action by a corporate officer or employee to establish a violation of the Act by that person:

> "[t]he jury should be instructed that a finding of guilt must be predicated upon some wrongful action by [the individual defendant]. That action may be gross negligence and inattention in discharging his corporate duties and obligations or any of a host of other acts of commission or omission which would 'cause' [the violation]." 499 F.2d at 842 (footnotes omitted).

This conclusion is consistent with the plain language of the statute. Section 301, which is subtitled "Pro-

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[13] Letter to Bishop Mandell Creighton, 1887.

hibited Acts," begins: "[t]he following acts and the causing thereof are hereby prohibited . . . ." The "acts" enumerated thereafter include the "failure" to do certain things. Thus, the term "acts" encompasses acts of omission as well as acts of commission. However, there is no language in Section 301 which even remotely suggests that criminal liability determined without regard for intent or knowledge can be predicated merely on an individual's titular position in a business organization.

The Court of Appeals' conclusion is also consistent with settled doctrines of criminal law. It is a fundamental tenet that conviction of a crime requires proof of both the *actus rea* and the *mens rea*.[14] A limited exception exists for what have come to be called "public welfare offenses."[15] In these cases, it has been held that the legislature may properly eliminate the usual requirement that the Government prove the defendant's intent or knowledge (*mens rea*) because the purpose of such statutes is to protect the public, not to punish an evil doer.[16] Since intent is considered irrelevant, the requirement that the Government prove intent is eliminated in order to ease the burden of securing convictions and thereby increase the efficiency of enforcement.

This concept, which is discussed more fully below,[17] appears to have become established as a limited exception to the general concepts of criminal jurisprudence.

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[14] 4 W. BLACKSTONE, COMMENTARIES *21.

[15] *See* Sayre, *supra* n. 11.

[16] United States v. Balint, 258 U.S. 250 (1922).

[17] See pp. 24-27 *infra*.

It was against this background that this Court in *Dotterweich* construed the Act as eliminating the requirement that the Government prove intent or knowledge in criminal prosecutions thereunder. As recognized by the Court of Appeals, however, while *Dotterweich* did away with the need to prove "awareness of wrongdoing," it did not dispense with the need to prove "wrongful action." 499 F.2d at 842.

In *Dotterweich,* the Court stated that individual criminal liability under the Act reaches "all who according to settled doctrines of criminal law are responsible for the commission of a misdemeanor." 320 U.S. at 284. The Court went on to clarify this reference to "settled doctrines," stating:

> "[t]o speak with technical accuracy, under § 301 a corporation may commit an offense and all persons who aid and abet its commission are equally guilty." *Id.*

A brief review of the "settled doctrines" to which the Court referred, and in particular the standards for determining those liable as aiders and abettors, dispels any doubt that the Government must, in each case, prove an act of commission or omission. In *United States* v. *Peoni,* 100 F.2d 401 (2d Cir. 1938), Judge Learned Hand considered the circumstances under which an individual, while not the principal perpetrator of an offense, could nonetheless be held criminally liable as an accessory, particularly as one who "aids" or "abets." Noting that the doctrine was established by the beginning of the Fourteenth Century, Judge Hand reviewed its development to modern times and concluded:

> "[i]t will be observed that all these definitions . . . demand that he in some sort associate himself with

> the venture, that he participate in it as in something that he wishes to bring about, that he seek by his action to make it succeed." 100 F.2d at 402.[18]

Dotterweich did not construe the Act as eliminating the requirement that the Government prove some act of commission or omission by the individual defendant. On the contrary, the Court there declined,

> "[t]o attempt a formula embracing the variety of *conduct* whereby persons may responsibly contribute in furthering a transaction forbidden by [the] Act . . . ." 320 U.S. at 285 (emphasis added.)

That *Dotterweich* did not so construe the Act has also been recognized by several later cases in this Court which have relied upon or considered *Dotterweich*. In *Lambert* v. *California*, 355 U.S. 225 (1957), this Court struck down, as a violation of the due process clause of the fourteenth amendment, the conviction of an individual under a provision of the Los Angeles municipal code which made it a crime for a person convicted of a felony to be in Los Angeles for a period of more than five days without registering with the chief of police. The prosecution had proved only that the individual was a convicted felon and a long time resident of Los Angeles and that she had not registered. It was established that she had "no actual knowledge of the requirement that she register . . . [and] . . . no showing [was] made of the probability of such knowledge." 355 U.S. at 227. The Court distinguished this situation from the circumstances justifying a conviction under *Dotterweich* stating:

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[18] This language was quoted with approval in Nye & Nissen v. United States, 336 U.S. 613, 619 (1949).

> "we deal here with conduct that is wholly passive—mere failure to register. It is unlike the commission of acts, or the failure to act under circumstances that should alert the doer to the consequences of his deed . . . . *United States* v. *Dotterweich,* 320 U.S. 277, 284." 355 U.S. at 228.

In *United States* v. *Wise,* 370 U.S. 405 (1962), where the issue was whether a corporate officer could be held individually criminally liable under § 1 of the Sherman Act, 15 U.S.C. § 1 (1970), for actions taken solely in a representative capacity, the Court stated:

> "[f]ollowing *Dotterweich,* we construe § 1 of the Sherman Act in its common-sense meaning to apply to all officers who have a responsible share in the proscribed transaction. Cf. *Carolene Products Co.* v. *United States,* 323 U.S. 18, 21.
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> . . . .
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> . . . we hold that a corporate officer is subject to prosecution under § 1 of the Sherman Act whenever he . . . participates in effecting the illegal contract, combination, or conspiracy—be he one who authorizes, orders, or helps perpetrate the crime—regardless of whether he is acting in a representative capacity." 370 U.S. at 409-16.

The Government's present position on this issue is far from clear. Initially, it asks the Court to interpret the Act as eliminating the need to prove "*particular* acts of omission or commission" (Govt. Brief at 2) (emphasis added). There would be no purpose in adding the qualifying phrase "particular" if the Government did not concede that it is required to prove some acts of omission or commission. Yet the Government never squarely addresses the issue of what showing is enough.

At one point the Government argues that "affirmative 'wrongful action' by the accused is not required" (Govt. Brief at 24); but this is conceded by all. The Court of Appeals plainly stated that the necessary "wrongful action" could be "any of a host of . . . acts of . . . omission." 499 F.2d at 842. The Government also admits that it "must offer proof of *actual* supervisory responsibility relating to the prohibited conditions" (Govt. Brief at 25) (emphasis added), and disclaims any intention of attempting to base a conviction solely on Mr. Park's position as president of the corporation.

Yet at trial, the only evidence introduced in the Government's case-in-chief tending to show that Park had *any* supervisory responsibility for sanitation was evidence that Park was Acme's president and the testimony of Acme's General Counsel that the corporation's by-laws provided that as president, Park "shall, subject to the board of directors, have general and active supervision of the affairs, business, offices, and employees of the company." (Govt. Brief at 6-7).

It would be difficult to find a chief executive officer of any business corporation whose duties were not described by the company's by-laws in substantially similar terms. If, in the Government's view, proof that the defendant is the corporation's chief executive officer is synonomous with proof of actual supervisory responsibility—the Government's offer to prove actual supervisory responsibility and its denial that it seeks to rely merely on titular responsibility is disingenuous.

In contrast to the Government's inability to articulate, in a meaningful way, the nature of any act of commission or omission which it must prove to obtain con-

viction of an individual, the Court of Appeals has formulated a standard which is not only clear but also has the advantage of being a traditional judicial standard, familiar to both judges and juries. That standard is causation. It presents the trier of fact with a very practical question: was the violation caused by, in whole or in part, an act of commission or omission by the defendant? Judges and juries have for centuries dealt with essentially this question in thousands of cases. There is no reason to believe that the standard should now prove unequal to the task.

It should also be recognized that judges and juries are also experienced with causation which may be indirect or contributory. Contrary to suggestions in the Government's brief (Govt. Brief at 38), the Court of Appeals did not suggest that the defendant's act of commission or omission must be related to the contamination of a specific lot of food or a specific shipment of a misbranded drug. It is sufficient to show that the defendant's act resulted in a situation, the natural consequence of which was the particular violation alleged. If the Government's real concern about proof of "particular acts of omission or commission," is that they will always have to prove direct causation, then the differences between the Government's position and the standard announced by the Court of Appeals is insignificant.

If on the other hand, the Government's true posture is that it need not prove *any* act of commission or omission by the individual, but rather only a "responsible relation" to the violation, assessed solely in light of the individual's position within the corporation, this is not only contrary to the language of the Act and

Dotterweich, it bears no rational relation to the purpose of the statute.

The principal purpose of criminal prohibitions, whether "public welfare offenses", common law or statutory offenses, is to influence conduct—deter individuals from doing certain acts and stimulating them to do others. If one refrains from the prohibited and accomplishes that which is required, one cannot properly be punished. Criminal liability, unrelated to acts of commission or omission, cannot deter individuals from doing certain acts or stimulate them to do others.

There is nothing illegal about being president of a supermarket chain. Nor is there anything *per se* illegal about being president of a supermarket chain which, as a corporation engaged in a generally lawful business, nonetheless violates the Act. For the criminal law was never intended to affect mere status. Mere status is neither good nor bad in the abstract. Therefore, a standard which imposes criminal liability on individuals on the basis of mere status, *wholly without regard to conduct*, bears no rational relation to the purpose of the statute. Certainly that standard should not be declared to be the law in the absence of the clearest expression by Congress of an intent to legislate in so novel a fashion.

II. Criminal Penalties Should Not Be Inflicted on Individuals Who Have Met the Standards of Conduct Which Congress Sought To Promote by the Act.

The Court of Appeals held that, in addition to proving an act of commission or omission by an individual, the Government must also prove that the act was "wrongful." 499 F.2d at 842. In a footnote, the Court of Appeals defined "wrongful action" as acts

which "cause" a violation. *Id.* at 841. The use of the term "wrongful" in the text indicates, however, that the Court of Appeals was sensitive to the fact that there should be *some* showing that the individual's behavior fell short of the standard of conduct which Congress sought to promote by the Act.

There is no rational basis for punishing an individual whose conduct meets that standard. To do so would "so outrage the feelings of the community as to nullify [the Act's] enforcement."[19] It is not clear that the Government disagrees with the Court of Appeals' suggestion on this point. Sufficient confusion exists, however, and the point is important enough to merit this Courts' consideration and resolution of the issue.

At the beginning of this century, Congress sought to protect the public from impure or dangerous foods and drugs by enacting several statutes making distribution of these articles in interstate commerce a criminal offense. Among these statutes were the original Food and Drugs Act of 1906[20] and the Narcotics Act of 1914.[21] Neither statute contained explicit requirements that violations be committed "knowingly" or "willfully."

United States v. *Balint*, 258 U.S. 250 (1922), the seminal case in the area, involved a prosecution under the Narcotic Act of 1914 for the unlawful distribution of narcotic drugs. The defendants objected that the indictment failed to allege that they knew that the

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[19] Sayre, *supra* note 11, at 56.

[20] Federal Food and Drugs Act of June 30, 1906, ch. 3915, 34 Stat. 768.

[21] Narcotic Act of December 17, 1914, ch. 1, 38 Stat. 785.

drugs were narcotics. The Court found the indictment adequate, stating:

> "[w]hile the general rule at common law was that the *scienter* was a necessary element in the indictment and proof of every crime, and this was followed in regard to statutory crimes even where the statutory definition did not in terms include it (*Reg.* v. *Sleep,* 8 Cox C.C. 472), there has been a modification of this view in respect to prosecutions under statutes the purpose of which would be obstructed by such a requirement. It is a question of legislative intent to be construed by the court." 258 U.S. at 251-52.

The Court held that Congress had eliminated the requirement that the Government prove knowledge or intent, observing "the emphasis of the statute is evidently upon achievement of some social betterment rather than the punishment of the crimes . . . ." *Id.* The Court concluded:

> "where one deals with others and his mere negligence may be dangerous to them, as in selling diseased food or poison, the policy of the law may, in order to stimulate proper care, require the punishment of the negligent person though he be ignorant of the noxious character of what he sells. *Hobbs* v. *Winchester Corporation,* [1910] 2 K.B. 471, 483.
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> . . . .
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> . . . Doubtless considerations as to the opportunity of the seller to find out the fact and the difficulty of proof of knowledge contributed to this conclusion." 258 U.S. at 252-54.

But the principle enunciated in *Balint,* and upon which the *Dotterweich* decision rests, finds its limita-

tions in its rationale. If the purpose of criminal sanctions is to "stimulate proper care," there is no basis for applying them to those who neither know nor should know that any special precautions or corrective measures are called for. Individuals cannot be "stimulated" by the threat of criminal sanctions of which they are unaware. An individual's awareness of a problem is a necessary prerequisite of his awareness of the potential criminal consequences of his conduct in relationship to that problem. In short, individuals should be held criminally liable only if the consequences of their conduct were reasonably foreseeable. If they could not have reasonably foreseen the violation, in the language of *Dotterweich*, they did not have "the opportunity of informing themselves of the existence of [the] conditions" which might result in that violation. 320 U.S. at 285.

The Government acknowledges the relevance of foreseeability:

> "Officials . . . who were totally unaware of any problem and could not have been expected to be aware of it in the *reasonable* exercise of their corporate duties, are not the subject of criminal action." Govt. Brief at 31 (emphasis added).

To similar effect is this Court's opinion in *Lambert* v. *California*, 355 U.S. 225 (1957), which indicated that *Dotterweich* was limited to situations involving

> "the commission of acts, or the *failure to act under circumstances that should alert the doer to the consequences of his deed.*" 355 U.S. at 228 (emphasis added).

The Court of Appeals for the District of Columbia Circuit has also interpreted *Dotterweich* as requiring

foreseeability. In *Belsinger* v. *District of Columbia,* 436 F.2d 214 (D.C. Cir. 1970), the court overturned an action by the Electrical Board of the District of Columbia suspending the master electrician specialist license of an individual. The individual was the president of a company, the employees of which had made electrical connections for gasoline stations without obtaining required permits. The court stated:

> "[i]f the Board is seeking to penalize appellant Belsinger based on his position as president of the Maintenance Corporation, it must prove that he either knew or should have known of the forbidden and dangerous work being done by employees of the Maintenance Corporation, and took no action to stop it." 436 F.2d at 220 (citing *Dotterweich).*

Just as there is no purpose in punishing individuals for unforeseeable consequences of their acts or omissions, those who are aware of potential problems and do those things which can reasonably be expected to prevent them, should not be the subject of criminal punishment, even if an occasional violation occurs despite their efforts. For once a person has taken reasonable precautions to prevent violations of the Act, at that point, threat of criminal sanction, however severe, cannot stimulate greater care.

This was recognized, at least implicitly, in *Morissette* v. *United States,* 342 U.S. 246 (1952), in which this Court observed that in public welfare offenses, where the requirement that the Government prove intent or knowledge is eliminated,

> "[t]he accused, if he does not will the violation, usually is in a position to prevent it with no more care than society might reasonably expect and no more exertion than it might reasonably exact from

one who assumed his responsibilities." 342 U.S. at 256.

Subsequently, in *United States* v. *Wiesenfeld Warehouse Co.*, 376 U.S. 86 (1964), this Court applied that limitation to the Act, noting that the Act's criminal sanctions were not intended to apply to those who are "'powerless' to protect against" the violation. 376 U.S. at 91.

While the Government's Brief recognizes that criminal liability can attach only to those officers and employees who have the power to prevent violations (Govt. Brief at 14, 22), there is a suggestion that the power need only be titular and theoretical and that if a violation occurs, individuals with such theoretical power should be subject to criminal penalties, including imprisonment, despite the fact that they may have taken every reasonable precaution to prevent the violation. Not only does this position bear no rational relation to the purpose of the statute, the legislative history of the Act does not support the conclusion that Congress intended this result.

There is nothing in the legislative history of the 1938 Act which suggests that Congress intended to create standards of individual criminal liability which would punish persons who had taken reasonable precautions to comply with the Act. Indeed the Senate Report on S. 2800, one of the bills from which the 1938 Act evolved, suggests the opposite conclusion.[22] In commenting on a provision which increased penalties for violations committed "with the intent to defraud or mislead," the Report contrasted such "willful" viola-

[22] S. Rep. No. 493, 73d Cong. 2d Sess. 20 (1934).

tions with those which occur "through inadvertence, carelessness, or negligence." Each of these three phrases connotes a *failure* to exercise proper care and strongly suggest that Congress did not envision the criminal prosecution of individuals who take proper care.[23]

The legislative history of the subsequent amendments and proposed amendments to the Act cited by the Government (Govt. Brief at 29-30) similarly does not support the view that Congress intended to endorse a standard of criminal liability which would punish individuals who have exercised proper care. When, in 1948, Congress considered amendments to the Food, Drug, and Cosmetic Act, in the form of S. 1190 and H.R. 4071, its principal concern was the effect of the decision in *United States* v. *Phelps-Dodge Mercantile Co.*, 157 F.2d 453 (9th Cir. 1946), *cert. denied*, 330 U.S. 818 (1947), which narrowly limited the application of the adulteration provisions of the Act. The issue of individual criminal liability was not even considered in the House.[24] The Senate passed the so-called Moore Amendment,[25] which was added from the floor [26]

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[23] Webster's New International Dictionary (2d ed. unabridged 1954) defines inadvertence as:

> "1. The fact or action of being inadvertent; lack of heedfulness or attentiveness; inattention. 2. An effect of inattention; a result of carelessness; an oversight, mistake, or fault from negligence. Syn.—Heedlessness, carelessness, thoughtlessness. See NEGLIGENCE. Ant.—Care, diligence, assiduity, carefulness."

[24] *Hearings on H.R. 3128 and H.R. 3147 Before a Subcomm. of the House Comm. on Interstate and Foreign Commerce*, 80th Cong., 1st Sess. (1947); 94 CONG. REC. 134-137 (1948).

[25] 94 CONG. REC. 8239 (1948).

[26] 94 CONG. REC. 6760-61 (1948).

and which would have required a showing of "willfulness' or "gross negligence" prior to a criminal prosecution of *any* "person". *Id.* While this amendment was dropped in conference, the Conference Report makes no mention of the reason for its deletion.[27]

Even if one accepts the Government's characterization of these events as a Congressional "refusal" to adopt the standard of the Moore Amendment (Govt. Brief at 30), that is irrelevant. Refusing to require the Government to prove "willfulness" or "gross negligence" in prosecutions of individuals *and* corporations is far different from authorizing conviction of an individual in the face of a showing that that individual has done those things reasonably within his power to prevent violations of the Act.

III. Requiring that a Conviction of an Individual Be Based on His Wrongful Action Will Not Interfere with Effective Enforcement of the Act.

A requirement that an individual's criminal conviction rest on proof of some act of commission or omission by that individual will not hinder effective enforcement of the Act. Nor will a requirement that the conduct must fall below the standards which Congress sought to promote by the Act. The problems which the Government suggests would result from observing these requirements are more imagined than real, and both requirements are entirely consistent with the Government's announced and actual enforcement policies.

A. THE DECISION OF THE COURT OF APPEALS CONCERNS ONLY ONE OF THE FDA'S SEVERAL ENFORCEMENT TOOLS.

In addition to criminal prosecution of corporations and corporate employees, the Act provides both judi-

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[27] H. R. REP. No. 2400, 80th Cong. 2d Sess. (1948).

cial and non-judicial sanctions. Moreover, the FDA has developed highly effective non-statutory remedies against the distribution of illegal articles. Under Section 304 of the Act, goods that the FDA believes violate any of the statutory or regulatory standards may be seized while held for introduction into commerce, while in commerce, or while held for sale after shipment in commerce, regardless of the number of transfers of ownership that have taken place.[28] Where goods are dangerous to health, the FDA is authorized under Section 304(a)(1)(B), to make multiple seizures wherever the goods may be found.[29] This remedy can bar the shipment of a warehouse of goods assertedly underprocessed, or can sweep from supermarket shelves a product using an unapproved additive.

The FDA also has two forms of injunctive relief available to it. Under Section 302 of the Act, it can move in court to enjoin corporations and individuals from violating any of the prohibited acts, including the delivery for introduction of any goods that are misbranded or adulterated.[30] This authority can effectively close down a food processing operation, and in the case of one dependent upon seasonal harvesting of agricultural raw materials, could be in fact ruinous. In the case of canned food, the FDA has exercised its special statutory authority to monitor the adequacy of the crucial thermal processing system.[31] Under Section 404 of the Act, deviations from required processing steps can result in an administrative order barring the firm from

[28] 21 U.S.C. § 334 (1970).

[29] 21 U.S.C. § 334(a) (1) (B) (1970).

[30] 21 U.S.C. § 332 (a) (1970).

[31] 21 U.S.C. § 344 (1970); 21 C.F.R. Part 90 (1974).

shipping goods in commerce until, under a "permit", the FDA determines that adequate processing is being done.

The FDA has the final statutory remedy under Section 705 of publicity.[32] The agency is permitted to publicize through every type of media instances where health hazards or gross fraud may exist. The effects of publicity can ruin trademarks and devastate seasonal sales.

In addition to these explicit statutory remedies, the FDA has developed a number of non-statutory but often equally effective procedures for protecting the public from illegal articles. The foremost of these is the "recall," which, under the FDA, has been carefully stratified according to the severity of the problem, the scope of merchandising outlets to be canvassed for the goods, and the degree of publicity to be used. Under the threat of the full panoply of judicial sanctions, firms thus use their own resources in what amount to self-imposed injunctions and multiple seizures.

All of the foregoing sanctions apply regardless of the potential or actual imposition of criminal sanctions. They apply completely to the violative goods and not to individuals. They apply, however, with often devastating economic consequences—to particular brands of products, to particular lines of products, and indeed at times even to companies as a whole. It is against this panoply of enforcement powers that FDA's need for individual criminal prosecutions, and their impact on the individuals involved, must be considered.

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[32] 21 U.S.C. § 375 (b) (1970).

B. A STANDARD BASED ON CONDUCT WILL NOT PLACE SERIOUS BURDENS ON GOVERNMENT PROSECUTORS.

The Government exaggerates the burden which would be placed on prosecutors by a standard requiring proof of an act of commission or omission by the individual. As noted above, the Government's suggestion that it would be required to show an "affirmative 'wrongful action' by the accused" (Govt. Brief at 24) is negated by the Court of Appeals' statement that it would be sufficient to show "any of a host of . . . acts of commission or omission which would 'cause' the [violations]." 499 F.2d at 842. Similarly, the Government's complaint that the Court of Appeals' standard would require proof, in food cases, of an act of commission or omission directly related to a "particular lot of flour or breakfast cereal" is unwarranted. Govt. Brief at 38. Nothing in the Court of Appeals' opinion suggests that in food adulteration cases growing out of insanitary storage conditions, the Government would have to show more than the foreseeability of the insanitary conditions by the individual and his failure to take reasonable preventive or corrective measures which were within his power to institute.

C. A STANDARD BASED ON CONDUCT WILL NOT PERMIT CORPORATE OFFICERS TO "ISOLATE" THEMSELVES FROM CRIMINAL LIABILITY.

Contrary to the Government's assertion, a standard of individual criminal liability based on the individual's conduct would not encourage corporate officers and employees to "isolate" themselves from possible liability. As a practical matter, those situations which may give rise to violations of the Act by the corporation are so inexorably woven through the fabric of the entire business enterprise that corporate officers and other management personnel could not "isolate" them-

selves from potential violations of the Act without so isolating themselves from the general conduct of the corporation's business as to be unable to function effectively in their executive positions.

Even if individuals in top management were to attempt to carve out responsibility for compliance with the Act and delegate it away, in the case of intentionally fraudulent or flagrant violations, they will almost certainly nonetheless have actual knowledge of the violation. If they have purposefully isolated themselves from even knowledge of intentionally fraudulent and flagrant violations, that act alone could be sufficient to support the imposition of individual criminal liability for the corporate violation since the very act of "isolation" is itself suggestive of the foreseeability of the violation.

D. THE FDA'S ANNOUNCED AND ACTUAL ENFORCEMENT POLICY IS DIRECTED ONLY AT THOSE INDIVIDUAL CORPORATE OFFICERS AND EMPLOYEES WHOSE ACTS OF COMMISSION OR OMISSION CAUSE VIOLATIONS OF THE ACT AND FALL SHORT OF THE STANDARD OF CONDUCT WHICH CONGRESS SOUGHT TO PROMOTE BY THE ACT.

In its brief, the Government declares that it is,

> "FDA policy to limit prosecutions to continuing violations, violations of an obvious or flagrant nature, and intentionally false or fraudulent violations." Govt. Brief at 16.

A recent study of the agency's actual enforcement procedures confirms that they conform to this policy.[33] In particular, the study found that, except in extraordinary cases, "FDA policy provides for a 'warning' to potential defendants and an opportunity to comply vol-

[33] O'Keefe and Shapiro, *supra* note 7.

untarily." *Id.* at 25. Review of a sample of unreported cases showed that,

> "[i]n every case some form of warning and follow-up inspection was provided . . . . Indeed, given the warnings and subsequent acts of omission in a number of instances, it could be said there were both awareness of wrongdoing and wrongful action on the part of individuals prosecuted in these cases." *Id.* at 30.

Thus the Government's enforcement policies are consistent with a requirement that it prove an act of commission or omission by the individual. Barring the exceptional circumstance where an employee engages in a frolic of his own, if a corporate violation is intentionally fraudulent or flagrant, the Government should have little difficulty in convincing a jury that top corporate officials either knew of the violation, or at least failed to take reasonable precautions to prevent the violation.

IV. It Is "An Arrogant Assertion that It Is Proper To Visit the Moral Condemnation of the Community Upon One of Its Members on the Basis Solely of the Private Judgment of His Prosecutors." [34]

The Government argues that there is no difficulty in reading into the Act a Congressional intent to subject individuals to a standard of criminal liability, where guilt turns on the defendant's corporate position, without regard to conduct, because the individual's rights will be protected by "the good sense of prosecutors." Govt. Brief at 31. While prosecutorial discretion is recognized as a necessary if not always heralded

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[34] Hart, *supra* note 12, at 424.

aspect of our criminal system, as noted by Professor Hart, the implications of the Government's suggestion are staggering.

Given the ease with which the FDA can discover at least one violation of the Act by a company engaged in the manufacture or distribution of foods, drugs, cosmetics, or medical devices, regardless of the care the president of the corporation may have taken to prevent the violation—under the standard urged by the Government, there is nothing which the president can do to avoid conviction, a fine and possible imprisonment, beyond trusting in the goodwill of the FDA. The concept of individual civil liberties existing at the discretion of any executive agency of government is repugnant to this country's entire judicial and political heritage. While no suggestion is made that the FDA or the Department of Justice seek this power to abuse it, where the harsh operation of the law is realistically and admittedly stayed only by the discretion of those charged with its enforcement, the rights of individuals have no real substance.

V. The Jury Instruction Given at Park's Trial Improperly Focused Almost Entirely on Park's Corporate Position and Probably Led the Jury to Convict Park Solely on that Basis.

Viewed in the light of the requirement of the Act, that the conviction of an individual must rest on proof of his wrongful conduct, as properly enunciated by the Court of Appeals, the trial court's instruction to the jury was so prejudicially confusing as to require that Park's conviction be reversed. The thrust of the instruction was that Park could be found guilty "by virtue of his position in the company." App. 62.[35] Under

[35] References designated "App." are to the printed Appendix filed by the Government in this case on December 26, 1974.

the instruction, the jury could have convicted Park even though it believed that he was guilty of neither acts of commission nor omission related to the corporate violations.

Comparison of the instruction given at Park's trial with the instruction given in *Dotterweich* does not save it. In *Dotterweich,* no attempt was made to equate Dotterweich's guilt or innocence with his position in the company. Rather the court posed the issue in terms of "[w]as he responsible for the shipment . . . [i]n other words . . . were [they] made under his supervision by him as 'General Manager' " [36]

One cannot read the instruction in *Dotterweich* and escape the conclusion that the trial court clearly indicated to the jury that to convict it had to find that the defendant personally participated in the violation, at least to the extent of authorizing his agents to do the acts on his behalf.

The instruction at Park's trial clearly focused the jury's attention on Park's corporate status. In *Dotterweich,* the court only cautioned the jury that the defendant need not have "personally and physically made the shipment himself," and no suggestion was made that Dotterweich need not have participated in the violation. In contrast, in Park's case, the trial court on *two* occasions told the jury that "he need not have personally participated in the situation." App. 62. The only additional guidance which the trial court gave, other than telling the jury that they were not *compelled* to convict on the basis of Park's title alone, was that Park had to have had a "responsible relation to the

[36] The text of the jury instruction given in *Dotterweich* appears as a footnote in the Government's Brief at page 24.

situation." *Id.* There was no further explanation of what constituted such a "responsible relation" and the trial judge specifically denied a request for further definition. App. 62-63. In the context of a charge dominated in the beginning by repeated references to the defendant's corporate position and the irrelevance of personal participation, the jury could easily have equated the issue of "responsible relation" with the fact of Park's corporate position and not as a direction to determine guilt or innocence in terms of Park's conduct. As the Court of Appeals found:

> ". . . the court told the jury that Park would be guilty if it were shown that he 'had a position of authority and responsibility in the situation out of which these charges arose.' This instruction, taken in combination with the other parts of the charge related above, might well have left the jury with the erroneous impression that Park could be found guilty in the absence of 'wrongful action' on his part." 499 F.2d at 841-42.

Since there is then a substantial probability that the jury convicted Park solely on the basis of his corporate status, the conviction cannot stand. "A conviction ought not to rest on an equivocal direction to the jury on a basic issue." *Bollenbach* v. *United States,* 326 U.S. 607, 613 (1946).

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeals should be affirmed.

Respectfully submitted,

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